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Food and Drug Administration  
510(k) Notification - Richards Total/Partial Prosthesis  
June 28, 1996

K962564

Smith & Nephew ENT

Smith & Nephew Richards Inc.  
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**Smith+Nephew**

## 510(k) Summary of Safety and Effectiveness

Trade Name: Richards Total/Partial Prosthesis  
Common Name: Partial Ossicular Replacement Prosthesis  
Total Ossicular Replacement Prosthesis  
Classification Name: Partial Ossicular Replacement Prosthesis (§ 874.3450)  
Total Ossicular Replacement Prosthesis (§ 874.3495)  
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Date Prepared: June 28, 1996

The Richards Total/Partial Prosthesis is substantially equivalent to the Tilt-Top TORP and PORP marketed by Smith & Nephew ENT. These devices have the same indications for use, total/partial reconstruction of the ossicular chain that has lost its function due to disease, trauma, or congenital defect. The Richards Total/Partial Prosthesis and the predicate devices both have trimmable shafts made of Plasti-Pore and heads that may be tilted for proper angulation against the tympanic membrane. The head of the Richards Total/Partial Prosthesis is made from Hydroxylapatite, a widely accepted material for middle ear reconstruction.

Differences between the Richards Total/Partial Prosthesis and the predicate device should not affect the safety or effectiveness.